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10/553,818	02/08/2007	Evangelos Hytopoulos	SEEK-007	3991
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EXAMINER				
DEJONG, ERIC S				
ART UNIT		PAPER NUMBER		
1631				
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09/24/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/553,818

**Applicant(s)**

HYTOPOULOS, EVANGELOS

**Examiner**

ERIC S. DEJONG

**Art Unit**

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/CD)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_
- Paper No(s)/Mail Date: 12/17/2007 and 01/28/2008

## **DETAILED OFFICE ACTION**

Claims 1-24 are pending and currently under examination in the instant application.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 12/17/2007 and 01/28/2008 have been considered by the examiner.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant claims are directed to a method and the related system comprising the steps of deriving a biological dataset profile comprising output from 2 or more parameters, generating a prediction envelope that provides an upper and lower limited for experimentally observed variation, and an assessment of a test agent profile being different than a control biological dataset. While the instant claims require "deriving a biological dataset profile from an experimental system", the claims do not recite any positive limitation wherein actual, physical experiments are required to be performed in

order to practice the claimed invention. Rather, the instant claims only require the use of a biological data set profile. This is further evidenced by the system of claim 24 also requiring "deriving a biological data set" as it is recited in the method of claim 1. Since the system as claimed is not capable of performing an physical experiment, as the system is limited only to the execution of software instructions.

Further, the recited steps of the method of claim 1 and the steps carried out by the system of claim 24 are directed to a protracted series of abstract computational and mental consideration steps. The claims do not recite any positive limitation wherein a practitioner is required to perform physical steps directed to transforming a particular object into a different state or thing. Rather, the recited steps are directed only to abstract statistical calculations performed on data, per se. Further, the recited steps of the method of claim do not require the use of any particular machine or apparatus, but rather are only require that a specified series of statistical calculations are performed on biological dataset profiles, wherein the particular content of data contained in the profile is not specified. The system of claim 24 does expressly recite "a data processor comprising software for determination of functional homology between two agents by (an) algorithm. The algorithm is recited as comprising the exact same steps set forth in the method of claim 1. The Interim Guidelines for Determining Subject Matter Eligibility of published July 2010 sets forth the following factors that weigh against patent eligibility with regard to claim 24:

Insufficient recitation of a machine or transformation

-a machine is generically recited such that it covers any machine capable of performing the claimed step(s)

-a machine is merely an object on which the method operates.

With regard to claim 24, the claimed system recites generic data processor and software that is capable of applying an algorithm and, further, the recited machine elements of claim 24 are merely the vehicle on which an algorithm (comprising only a series of statistical calculations) is carried out.

For the above cited reasons, the instant claims are directed to nonstatutory subject matter because they encompass only a series of abstract computational and mental steps and any general purpose computer capable of performing said abstract computational steps.

Claims 1-24 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The instant claims are directed to a method and the related system comprising the steps of deriving a biological dataset profile comprising output from 2 or more parameters, generating a prediction envelope that provides an upper and lower limited for experimentally observed variation, and an assessment of a test agent profile being different than a control biological dataset. Further recited embodiments in dependent claims include additional statistical computations that are to be carried out. Further, while the preamble of independent claims 1 and 24 suggests the claims are directed to determining the functional homology between two agents, the recited steps that form

the body of the claim are not tied to any specific assessment of functional homology, but rather only recite a series of abstract, statistical calculations that, interpreted by their plain meaning, are not tied to nor specifically relate to an assessment of functional homology (see also the rejection of claims under 35 USC 112, 2<sup>nd</sup> paragraph below).

In practicing the invention as claimed, the result is the generation of a prediction envelope, although the claims do not specify to what the prediction is actually directed. The instant claims do not recite any particular improvement or resultant characteristic that is imparted to said prediction envelope nor how said prediction envelope is meaningfully tied to a prediction of functional homology. Further the instant claims do not specify how the resultant prediction envelope would be used to yield any useful information related to the functional homology of two agents. The Court of Patent and Appeals has stated:

"Practical utility is a shorthand way of attributing "real-world" value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." A 'use' to do further research is not considered a utility which provides an "immediate benefit" to the public.

Examples of situations requiring further research to identify or reasonably confirm a "real world" context of use, and which do not have utility under 35 USC 101, as set forth in MPEP 2107.01.1, include:

(A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved", and

(C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility.

The instant claims encompass a process of basic research (computational statistical analysis applied to a biological dataset profile) drawn to studying properties of two unspecified agents and as such do not result in an "immediate benefit" to the public. As noted in the utility guidelines (see Federal Register, December 21, 1999, Vol. 64, No. 244), basic research on a product to identify properties is an insubstantial utility (see

page 6 of the Utility guideline training materials). Therefore, the instant claims do not have a substantial utility.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-24 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 1 recites in the preamble a method of determining the functional homology between two agents. Similarly, independent claim 24 is drawn to a system for the determining the functional homology between two agents. However, the

recited steps of comprising the method of claim 1 and the recited steps carried out by the system of claim 24 are drawn only to the application of a protracted series of statistical calculations that operate on a biological dataset profile. The recites computational steps of the claims as well as the agents, parameters, and calculated values are not tied, either expressly or inherently, to the functional homology to which the invention is directed to as indicated in said preambles. Rather, practicing the invention of claim 1 results only in the calculation of an unspecified prediction envelope. Similarly practicing the invention of claim 24 results in a system that carries out a series of computational steps that results in a unspecified prediction envelope. This causes the metes and bounds of the instant claim to be indefinite because it is unclear if the scope of the instant claims is directed only to the series of statistical computations applied to an unspecified series of biological dataset profile or, alternatively, if the recited series of statistical computations is limited to a determination of functional homology.

For the benefit of applicants, if the instant claims are intended to be directed to a determination of functional homology, then the claims should be amended so as to recite positive limitation therein that specifically tie the recited computational steps and elements thereof to the specific task of determining functional homology. As the claims stand, they are directed to a protracted series of statistical calculations generated from a biological data profile, the content of which is not specified, that, when practiced, does not result in the determination of the functional homology between to agents, as suggested by the preamble of the instant claims. Further, claims 2-23 are also included under this rejection due to their dependence from independent claim 1.



Because of the above identified issues with the claims rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, a meaningful search of the prior art cannot be performed at this time in the instant application.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. DEJONG whose telephone number is (571)272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/ERIC S. DEJONG/  
Primary Examiner, Art Unit 1631